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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,109	03/26/2004	Jean Francois Bach	IVD938 US PCT	8031

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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	PAPER NUMBER
1646	

NOTIFICATION DATE	DELIVERY MODE
03/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/810,109	**Applicant(s)** BACH ET AL.	
	Examiner Bruce D. Hissong, Ph.D.	**Art Unit** 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 December 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 35 USC 112, 2nd paragraph.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: *13*.
   Claim(s) rejected: *2-4,6,7,10,11,13-15 and 17-21*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

/Robert Landsman/
Primary Examiner, Art Unit 1647

Continuation of 13. Other: The response received on 12/13/2007 does not place the claims in condition for allowance for the following reasons:

Claims 2-4, 6-7, 10-11, 13-15, and 17-21 remain rejected under 35 USC 112, first paragarph, regarding lack of enablement for methods of treating all possible disorders resulting from failure of immunoregulation of CD4 T cells, or compositions for such treatment, or processes for producing such compositions, as set forth on pages 4-5 of the office action mailed on 6/13/2007. In the response received on 12/13/2007, the Applicants argue that inoperative embodiements are permitted, and thus undue experimentation would not be required to practice the claimed invention. These arguments have been fully considered and are not persuaive. As currently written, the claims read on any disease resulting from "failure of immunoregulation" of CD4 T cells, and any method which results in "affecting IL-4 production". Because immunoregulation can comprise regulation of any facet of CD4 activity, and the claims do not specify the type of immunoregulation which must fail, the breadth of the claims is excessive. The specification does not provide enablement for the current breadth of the claims regarding failure of all types or degree of immunoregulation. Furthermore, the claims read on any type or degree of "affecting IL-4 production", and thus read on methods which result in both increased and decreased production of IL-4. Although the specification teaches diseases which may benefit from increased IL-4, the specification does not teach how to treat diseases by decreasing IL-4 production.

Claims 2-4, 15, and 17 remain rejected under 35 USC 102(b) as being anticpated by both Grabstein (US 5,681,557) and Williams (5,032,396), as set forth on pages 7-8 of the office action mailed on 6/13/2007. In the response received on 12/13/2007, the Applicants argue that neither Grabstein nor Williams recite IL-4 production, and thus do not meet the limitations of the claims. These arguments have been fully considered and are not persuasive because the claims, as currently amended, recite methods which "affect IL-4 production". Because the claims do not specify the type or degree of affecting IL-4 production, any increase or decrease in IL-4 production would meet the claim limitations. Because both Grabstein and Williams teach adminstration of IL-7 to individuals, and said IL-7 administration would be expected, in the absence of evidence to the contrary, to affect IL-4 production by either increasing or decreasing production of IL-4, the methods of Grabstein and Williams would inherently meet thelimitations of the claims.

Claims 2-3, 6-7, 10-11, 13-15, and 17-21 remain rejected under 35 USC 103(a) as obvious in view of the combination of Gombert and Jicha, as set forth on pages 8-9 of the office action mailed on 6/13/2007. In the response received on 12/13/2007, the Applicants argue that the previous office action did not provide proof that Gombert is indeed proper prior art. Attached is the MEDLINE citation for Gombert, showing an electronic publication date (EDAT - see 4th line from the bottom) of 2/1/1996. Therefore, Gombert is in fact prior art and the rejection is accordingly maintained.

Claims 2-4, 15, and 17 remain rejected on the grounds of nonstatutory obviouness-type double patenting as being unpatentable over claim 1 of US 6,713,053. In the resonse received on 12/13/2007, the Applicants state that the filing of a terminal disclaimer will be considered when allowable subject matter is identified. Accordingly, the rejection is maintained.

Claims 2-4, 7, 10-11, 13-15, and 17-21 remain rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatenable over calim 1 of US 6,713,053 in view of Jicha. In the response received on 12/13/2007, the Applicants state that the filing of a terminal disclaimer will be considered when allowable subject matter is identified. Accordingly, the rejection is maintained.